PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2008/000233	21.02.2008	23.02.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/053 A61B5/029 A61B5/083

Applicant
CHEETACH MEDICAL LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

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Date of completion of this opinion
see form PCT/ISA/210

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-21
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-21
Industrial applicability (IA)	Yes:	Claims	1-21
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: LELE SUHAS S ET AL: "Exercise capacity in hypertrophic cardiomyopathy: Role of stroke volume limitation, heart rate, and diastolic filling characteristics" CIRCULATION, vol. 92, no. 10, 1995, pages 2886-2894, XP002487808 ISSN: 0009-7322

D2: WO 2006/087696 A (NEW LEAF CAPITAL LTD [GB]; KEREN HANAN [IL]; SIMON AVRAM B [GB]) 24 August 2006 (2006-08-24) cited in the application

D3: RAZA S B ET AL: "FILTERING RESPIRATION AND LOW-FREQUENCY MOVEMENT ARTEFACTS FROM THE CARDIOGENIC ELECTRICAL IMPEDANCE SIGNAL" MEDICAL AND BIOLOGICAL ENGINEERING AND COMPUTING, SPRINGER, HEILDELBERG, DE, vol. 30, no. 5, 1 September 1992 (1992-09-01), pages 556-561, XP000323425 ISSN: 0140-0118

D4: US-A-5 158 093 (SHVARTZ ESAR [US] ET AL) 27 October 1992 (1992-10-27)

D5: MIYAMOTO Y ET AL: "CARDIO RESPIRATORY DYNAMICS DURING SINUSOIDAL AND IMPULSE EXERCISE IN MAN" JAPANESE JOURNAL OF PHYSIOLOGY, vol. 33, no. 6, 1983, pages 971-986, XP008094022 ISSN: 0021-521X

2. The present application does not meet the criteria of the PCT, because the subject-matter of claims 1, 8 and 10 does not involve an inventive step in the sense of Article 33(3) PCT.

2.1 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):

A method of estimating exercise capacity of a subject, the method comprising: calculating cardiac output (Methods section, sub-heading "Study Protocol"), using said cardiac output for estimating the exercise capacity of the subject

(Discussion section, sub-heading "Limitation of Exercise Capacity in Hypertrophic Cardiomyopathy"; see also abstract).

2.2 The subject-matter of claim 1 therefore differs from this known method in that radiofrequency signals are used for measurement, and that the phase difference between transmitted and received signal is used to calculate cardiac output.

The problem to be solved by the present invention may therefore be regarded as providing an alternative, non-invasive method of cardiac output measurement
However, these features have already been employed for the same purpose in a similar method, see document D2, page 19, line 31 - page 20, line 18. It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a method according to document D1, thereby arriving at a method according to claim 1.

Hence, the solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT).

2.3 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claims 8 and 10, which therefore are also considered not inventive.
The additional features of claim 10 are disclosed in document D2 as follows (the references in parentheses refer to D1):

A system for estimating exercise capacity of a subject (21), comprising:
a radiofrequency generator (22) for generating output radiofrequency signals;
a plurality of electrodes (25) designed for transmitting said output radiofrequency signals (24) to the subject (21) and for sensing input radiofrequency signals (26) from the subject (21).

3.1 Dependent claims 2-6, 9-13, 15 and 20-21 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT) for the following reasons:

- Claims 2 and 9: see document D1, Methods section, sub-heading "Study Protocol".
- Claim 3: see document D2, page 19, line 31 - page 20, line 18 and Fig. 2.
- Claims 4 and 12: see document D2, page 20, line 19 - page 21, line 2.
- Claims 5 and 13: see document D2, page 21, lines 10-30.
- Claims 6 and 11: see document D1, Discussion section.
- Claims 7, 14, 16 and 17: see document D3, page 557, left column, paragraph 3 and page 558, right column, first paragraph.
- Claim 15: see document D2, page 20, lines 10-14.
- Claims 18 and 19 appear to relate to arbitrary choices for filter cut-off frequencies.
- Claims 20 and 21 appear to relate to well-known alternatives of what is disclosed in document D1, Methods section. See also document D5, page 973, paragraphs 2 and 3.

Re Item VIII

Certain observations on the international application

1. The term "exercise capacity" is rather vague. The description of the current application does not provide a definition of "exercise capacity", but rather mentions some properties. Document D4 gives a more precise indication of what "exercise capacity" could mean (see column 5, line 40 - column 6, line 28 and the example given in Fig. 5); however, it is not clear whether the intended meaning in the current application is the same as in document D4. Since no clearer definition of exercise capacity was available, it was assumed that the intended meaning of "exercise capacity" is that of document D4.

2. Claim 10 relates to a system which comprises the apparatus of claim 8. Therefore, claim 10 should be re-drafted as a claim dependent on claim 8, in order to fulfil the requirement of conciseness (Article 6 PCT), especially considering that "system" is the same claim category as "apparatus" (see PCT Guidelines 5.13).

3. Claims 7, 14 and 16 relate to a "dynamically variable filter". This expression is vague, because it does not say what kind of filter is used and in which way this filter is variable. According to the description of the current application, the filter "filters the data according to a frequency band which is dynamically adapted..." (page 10, lines 21-27). The fact that

the filter is characterized by a dynamically adapted frequency band is essential for solving the problem stated on page 10, lines 26-27 of the description and should be added to the above-mentioned claims.